

### C. Remarks

The claims are 56, 57, 60, 64, 66-68 and 74-83, with claims 74 and 83 being independent. Claim 74 has been amended to address the Examiner's §112 concern; no new matter has been added. Reconsideration of the pending claims is respectfully requested.

Claims 56, 57, 60, 64, 66-68 and 74-83 stand rejected under 35 U.S.C. §112, second paragraph, as being allegedly indefinite. While Applicant respectfully traverses this rejection, Applicant has amended independent claim 74 by removing the phrase "in a purified state" at each occurrence. Applicant respectfully submit that the removal of this phrase does not affect the scope of the presently pending claims since it is clearly set forth in claim 74 that the polylactide polymer is off-white to white in color and contains one or more metals in cationic form and that the one or more metals have a concentration up to 10 ppm. These claim limitations define "in a purified state". In view of Applicant's amendment of claim 74 to obviate the Examiner's concern, withdrawal of the §112 rejection is respectfully requested.

Claims 56, 57-58, 60, 64, 66-68 and 74-83 stand rejected under 35 U.S.C. §103(a) as being obvious over Bodmer (U.S. Patent No. 5,538,739) in view of Brich (GB 2,145,422) and Reiners (U.S. Patent No. 4,879,402) or Bendix (U.S. Patent No. 4,810,775) and further in view of Eliot (A Manual of Inorganic Chemistry, 1876) and as evidenced by Sigworth (J. Am. Water Works Ass'n., 1972). Applicant respectfully traverses this rejection.

At the outset, Applicant incorporates by reference herein the arguments advanced in previous responses. What is more, Applicant respectfully submits that the Examiner has not addressed in any detail Applicant's argument that this seemingly inherency-based rejection is flawed, given the simple fact that no combination of the cited references discloses or suggests the claimed pharmaceutical composition. Independent claim 74 is directed to a pharmaceutical composition with a very specific composition, namely (a) a polylactide polymer and (b) a hydrophilic or lipophilic drug. Importantly, the polylactide polymer (which is in a purified state according to the present invention) is an ester of a polyol containing at least three hydroxyl groups and is off-white to white in color; in addition, the polylactide in a purified state contains one or more metals in cationic form, where the one or more metals have a concentration up to 10 ppm.

With regard to the claimed metal concentration, the Examiner appears to be making the case that such a claim feature would be inherent in the polylactide polymers of the cited art since it would have been obvious to purify using activated charcoal (two points which Applicant expressly does not concede). However, as set forth in MPEP §2163.07:

"To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result

from a given set of circumstances is not sufficient.”” *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999)(citations omitted).

In this case, the Examiner is attempting to establish by possibility that a polylactide polymer of the cited art would have the claimed metal concentration. However, such a feature is not a given. For at least these reasons, Applicant respectfully submits that the cited combination of references fails to disclose or suggest all of the claim features and therefore requests withdrawal of the §103 rejection.

Claim 83 stands rejected under 35 U.S.C. § 103(a) as being obvious over Bendix in view of Sigworth. Applicant respectfully traverses this rejection.

The present invention as set forth in claim 83 is directed to a method of removing tin from a polylactide polymer comprising the step of contacting a polylactide polymer with activated charcoal to reduce tin concentration. The cited combination of references is deficient in certain key respects insofar as each of the two references fails to remedy the other's deficiency. Bendix may teach that activated charcoal can be used as a purification stage prior to an actual purification precipitation, but, as noted by the Examiner, Bendix contains no disclosure related to such a purification stage to remove tin. Sigworth, on the other hand, teaches that tin is readily adsorbed from a water sample onto carbon, but fails to teach or suggest that such a mechanism will work for a polylactide polymer. In fact, given Sigworth's statement that “it is very difficult in a given instance to predict what will happen” (at page 390) when using activated charcoal to purify in certain

settings, Applicant submits that there was no reasonable likelihood of success in using activated charcoal to reduce tin concentration in a polylactide polymer.

In the Response to Arguments section of the Office Action, the Examiner notes with respect to Bendix that “Clearly purification with activated charcoal is suggested. Since the teachings of Bendix et al teach that the purification is utilized to remove the residual monomer content as well as tin content (example 10), this suggests to one of ordinary skill that purification would lead to a reduction in both of these contents.” However, the Examiner overlooks the fact that Bendix equally clearly regards treatment with activated charcoal as optional (“[i]f it seems necessary” column 4) and that Example 10 makes no mention of treatment with activated charcoal whatsoever.

For at least these reasons, Applicant respectfully requests withdrawal of the §103 rejection.

In view of the foregoing amendments and remarks, favorable reconsideration and passage to issue is earnestly requested. Should the Examiner believe that issues remain outstanding, the Examiner is respectfully requested to contact Applicant's undersigned attorney in an effort to resolve such issues and advance the case to issue.

Applicant's undersigned attorney may be reached in our New York office by telephone at (212) 218-2100 or at the below listed address. All correspondence should continue to be directed to Novartis, Corporate Intellectual Property, One Health Plaza 104/3, East Hanover, NJ 07936-1080.

Respectfully submitted,

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